



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,778	04/02/2004	Gordana Vunjak-Novakovic	103248-010501	8172

615 7590 02/07/2008
JOHN S. HALE
GIPPLE & HALE
6665-A OLD DOMINION DRIVE
MCLEAN, VA 22101

EXAMINER

SINGH, SATYENDRA K

ART UNIT	PAPER NUMBER
----------	--------------

1657

MAIL DATE	DELIVERY MODE
-----------	---------------

02/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/815,778

Applicant(s)

VUNJAK-NOVAKOVIC ET AL.

Examiner

Satyendra K. Singh

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 12-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/04; 10/12/04; 2/3/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11 (applicant's elected invention of group Ia) are examined on their merits in this office action.

Election/Restrictions

Applicant's election **with traverse of Group Ia** (claims 1-12; directed to a **cartilage repair assembly**; elected specie of additive being "**growth factor**" for claim 11) in the reply filed on November 7th 2007 is acknowledged. The traversal is on the ground(s) of search and examination burden as follows:

"Applicant respectfully traverses the Examiner's further restriction requirement and election after the election of Group I. However, for purposes of responding to this action and to obtain examination, Applicant provisionally elects the invention of Group 1a, represented by claims 1-12 drawn to a cartilage repair assembly comprising an allograft bone plug, and an allograft milled cartilage mixture in a biocompatible carrier (as specifically recited in instant claim 1), classified in class 623, subclass 11.11 and various depending on the components. Group 1a - 1c is directed to a distinct cartilage repair assembly as indicated by the Examiner and there would not be a serious search and examination burden placed on the Examiner for examining 1a - 1c, if indeed there were any burden in undertaking such examination. The five cited reasons noted on page 5 of the restriction requirement are not applicable to the invention listed in 1a, 1b and 1c."

This is not found persuasive because burden lies not only in the search of US Patents, but in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, scope of enablement, and double patenting issues.

It is to be noted that applicants have elected the additive "growth factor" as specie for claim 11, but have failed to clearly point out how the elected specie reads on the pending claims (see applicant's response, page 2). Since, applicant's elected specie for an additive "growth factor" does not read on claim 12 (which depends from claim 11, and is directed to demineralized bone matrix, a non-elected specie), instant claim 12 has been withdrawn from further consideration as being directed to a non-elected invention.

Claims 1-11 (Group Ia, with elected specie of "growth factor") are examined on their merits in this office action, Hereafter.

The requirement (as previously made by the Examiner) is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "a cartilage repair **assembly**", which is confusing. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "cartilage repair **assembly**" in claim 1 is used by the claim to mean "a surgical implant", while the accepted meaning is "a cartilage repair **implant**." The term "cartilage repair assembly" is indefinite because the specification does not clearly redefine the term, and because the term "assembly" as recited could also mean "the fitting together of manufactured parts into a complete machine, structure, or unit of a machine; or a collection of parts so assembled", which

renders the claimed invention ambiguous. Appropriate correction/explanation is required.

In addition, claim 1 recites "said allograft bone plug having been treated to remove cellular debris and proteoglycans and an allograft milled cartilage mixture in a biocompatible carrier surrounding at least a portion of a side wall of said allograft bone plug", which is confusing. It is unclear as to what exactly is encompassed by the limitations as recited in the instant claim. It is not clear whether the "said bone plug is **being treated**" to remove cellular debris and proteoglycans" or to remove "allograft milled cartilage mixture in a biocompatible carrier" along with it. It is also not clear as to what **structural features** of the "cartilage repair assembly" are actually required by the limitations "...surrounding at least a portion of a side wall of said allograft bone plug" as presented in the instant claim, especially if the shape of the bone plug is cylindrical or oval (see instant claims 2 and 3). The claim 1, as recited, appears to be a product-by-process claim (see for example recitations of "said allograft bone plug being treated...", however, it fails to clearly and distinctly point out the structural features and their inter-relationship with each other (i.e. the components) in the product (i.e. the "cartilage repair assembly") as claimed. Appropriate explanation/correction is required.

Since, claims 2-11 depend from the broader claim 1, they are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 11 recites as follows:

"A cartilage repair assembly as claimed in claim 1 including an additive consisting of one or more of a group consisting of growth factors, human allogenic cells, human autologous bone marrow cells, human allogenic bone marrow cells, stem cells, demineralized bone matrix, cartilage, and insulin."

It is unclear as to what exactly is encompassed by the invention as claimed.

Applicants have elected a specie of the additive (as being "growth factor"), but 1) it is unclear if the additive is "further included" in the product or the broader claim 1 already encompasses such components; and 2) it is unclear if the product as claimed requires (i.e. "consisting of") only "growth factors" as an additive, or a combination of "growth factor" with "one or more" other components that are listed in the instant claim in an improper Markush claim (see also discussion above). Appropriate correction/explanation is required.

The instant claim 11 has been examined for the purpose of this office action as being directed to "growth factors", the applicant's elected specie.

As per MPEP 2173.05(h)- Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials. Inventions in metallurgy, refractories, ceramics, pharmacy, pharmacology and biology are most frequently claimed under the Markush formula but purely mechanical features or process steps may also be claimed by using the Markush style of claiming. See Ex parte Head, 214 USPQ 551 (Bd. App. 1981); In re Gaubert, 524 F.2d 1222, 187 USPQ 664 (CCPA 1975); and In re Hamisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980). It is improper to use the term "comprising" instead of "consisting of." Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931). The use of Markush claims of diminishing scope should not, in itself, be considered a sufficient basis for objection to or rejection of claims. However, if such a practice renders the claims indefinite or if it results in undue multiplicity, an appropriate rejection should be made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hart et al (US 5,782,835; [A]) taken with Bugbee (2000; [U]) in view of Peretti et al (2000; IDS).

Claims 1-11 are directed to “a **cartilage repair assembly** for repair of a defect in an articular cartilage comprising an allograft bone plug having a subchondral bone and an overlying cartilage cap, said autograft bone plug having been treated to remove cellular debris and proteoglycans and an allograft milled cartilage mixture in a biocompatible carrier surrounding at least a portion of a side wall of said autograft bone plug; wherein said allograft bone plug is cylindrically shaped; wherein said allograft bone plug has an oval shaped cross section; wherein said allograft bone plug has a cruciate shaped cross section; wherein said allograft bone plug has a scalloped shaped

cross section; a cartilage repair assembly as claimed in claim 2 wherein said allograft bone plug has a diameter ranging from 1 mm to 30 mm; wherein said allograft bone plug has a diameter ranging from about 4 mm to about 10 mm; wherein said milled cartilage is hyaline cartilage; wherein said milled cartilage is fibrocartilage; wherein said milled cartilage is a mixture of fibrocartilage and hyaline cartilage; and a cartilage repair assembly as claimed in claim 1 including an additive consisting of one or more of a group consisting of **growth factors** (applicant's elected specie), human allogenic cells, human autologous bone marrow cells, human allogenic bone marrow cells, stem cells, demineralized bone matrix, cartilage, and insulin".

*"[E]ven though **product-by-process claims** are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.1985).*

Hart et al [A] (while disclosing apparatus and methods for articular cartilage repair) teach a **cartilage repair implant** (in the form of a pre-shaped bone plug; see Hart et al, abstract, summary of the invention, lines 9-14, and column 3, 4th paragraph, in particular) comprising a sterile, cylindrical shaped structure made of subchondral bone and overlying integral hyaline cartilage cap, wherein said shaped structure has been dimensioned to fit in a drilled bore in a cartilage defect (in the form of a bone plug having a functional fit within the drilled bone hole; see Hart et al, columns 7-9, column 8, lines 50-55; and figures 8-9, in particular). Additionally, Hart et al [A] explicitly suggest the use of various **bio-adhesives** (known in the art to fill the gap between the plug and the hole in the native tissue structure), and additives with the bone plug, such as bone or cartilage **growth-promoting factors** (see Hart et al, column 9, 2nd paragraph, lines 18-24, in particular), including cartilage-derived growth factor, various interleukins, platelet-derived growth factor (PDGF), and bone morphogenic protein (BMP).

Bugbee [U] teaches fresh **osteochondral allografts** ("circular dowel-type" grafts or bone plugs used in the method of repair or treatment of articular cartilage defects in the knee; see page 158, summary, in particular) made of "living cartilage and a thin layer of underlying subchondral bone", and that have been **debrided** (see Bugbee, pages 159-160, section "technique", in particular) i.e. washed to remove marrow elements and made in the size and shape depending on the articular cartilage defect (see page 160, left column, in particular); wherein the allograft can be 'press fit' into the defect (if small defect), or may be fixed along with bioabsorbable pins used as supplemental fixation placed directly through the articular surface. Bugbee disclose the benefit of using "fresh osteochondral allografts" in terms of achieving much better long-term "chondrocyte viability" (known in the art for repair of the articular cartilage) and mechanical strength and support in the treated grafts during 10 year follow up documentation (see page 161, right column, in particular).

However, a "cartilage repair assembly" comprising an "**allograft milled cartilage mixture in a biocompatible carrier**" surrounding at least a portion of a side wall of the allograft bone plug (see instant claim 1) is not explicitly disclosed by the referenced inventions of Hart et al taken with Bugbee.

Peretti et al (IDS) disclose the use of cell-based tissue-engineered **allogeneic** implant material for cartilage repair in experimental animals, wherein the implant material comprises small pieces (lamb **articular cartilage pieces** between the range of **500 to 1000 microns**; see Peretti et al, abstract, page 567; Materials & Methods, page 568-572; and figure 1-2, in particular) of sterile, minced allograft cartilage mixed in **thrombin/fibrinogen solution** (i.e. a biocompatible carrier) with or without allogenic

chondrocyte cell preparation (see page 568, last paragraph, in particular) in a buffered solution containing appropriate antibiotics. Peretti et al conclude and explicitly suggest that a composite of fibrin glue and sterile, milled allograft cartilage pieces can effectively serve as a scaffold for chondrocyte transplantation, preserve the original phenotype of the chondrocytes, and maintain the original mass of the implant, which may represent a valid option for addressing the problem of articular cartilage repair (see Peretti et al, abstract on page 567, and discussion on pages 574-575, in particular). The claimed limitations of milled cartilage being hyaline and/or fibrocartilage are also met by the disclosure of Peretti et al, wherein the sterile, lamb cartilage chips or small pieces are used to obtain a cell-based allogenic implant construct, as discussed above.

Therefore, it would have been obvious to a person of ordinary skill in the clinical art (at the time this invention was made) to modify the cartilage repair assembly/implant of Hart et al (taken with the disclosure of Bugbee, as discussed above) such that the bone plug is surrounded using a mixture of **milled allograft cartilage pieces or mixture** in a biocompatible **carrier** (i.e. a solution containing thrombin and fibrinogen) surrounding at least a portion of a side wall of the bone plug, as explicitly disclosed by the invention Peretti et al.

One of ordinary skill in the clinical art would have been motivated to modify the cartilage repair assembly/implant of Hart et al (taken with the disclosure of Bugbee for the use of fresh osteochondral allografts that contain chondrocytes needed for cartilage repair) because the cited prior art references suggest the incorporation of chondrogenic factors (i.e. growth factors; Hart et al), and/or milled cartilage pieces along with allograft

chondrocyte cells (Peretti et al, in addition to the disclosure of Bugbee) in order to address the problems associated with the articular cartilage repair (i.e. by effectively serving as a scaffold for chondrocyte transplantation, preserving the original phenotype of the chondrocytes, and maintaining the original mass of the implant; see discussion, supra) with reasonable expectation of success.

Given the detailed teachings in the cited prior art references as discussed above, the limitations of claim 3-7 (i.e. various shapes of the allograft bone plug and diameter ranges) would have been obvious to a person of ordinary skill in the clinical art as evidenced by the fact that both Hart et al and Bugbee disclose cylindrical and circular dowel-type grafts (see Hart et al, figure 8, column 8, 2nd and 3rd paragraphs; and Bugbee, page 160, left column, in particular), the diameter ranges of which would have been obvious design choice depending on the type and measurement of the defects being treated, and were in fact well known in the art as disclosed by Bugbee (see page 160, in particular). In the absence of any evidence to contrary, the shape, size, and diameter ranges of the cartilage repair implants would have been obvious parameters for an artisan of ordinary skill in the clinical art to vary depending on the parameters of the defects being treated.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2144.06, "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: Generally, differences in concentration or temperature will not support

the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

For the substitution of art recognized functional equivalents-

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 16 of copending Application No. 10/960,960 (same assignee, common inventors). Although

the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the co-pending application are also directed to “a cartilage repair assembly comprising a sterile shaped structure of subchondral bone and overlying integral cartilage cap, said shaped structure been dimensioned to fit in a drilled bore in a cartilage defect are so that said shaped bone and hyaline cartilage cap when centered in the bore can be rotated in said bore, the shaped structure when placed in the bore forming a gap ranging from 10 microns to 2 mm, said bone plug being treated to remove cellular debris and proteoglycans and sterile milled allograft cartilage pieces mixed in a thrombin fibrinogen solution surrounding at least a portion of a side wall of shaped structure in said bore”. Since the two sets of pending claims are clearly co-extensive in scope, an ODP rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/438,883 (same assignee, common inventors). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the co-pending application are also directed to “a cartilage repair assembly for repair of a defect in an articular cartilage comprising a sterile allograft bone plug having a subchondral bone portion and an integral overlying cartilage cap, said allograft bone plug having been treated to remove cellular debris and proteoglycans and sized to have an interference fit in a drilled bore in a cartilage defect

area and allograft milled cartilage mixed in a biocompatible carrier placed in contact with said allograft bone plug in a defect area being repaired" (see claim 1, in particular).

Since the two sets of pending claims are co-extensive in scope, an ODP rejection is deemed proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

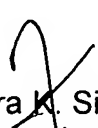
Conclusion

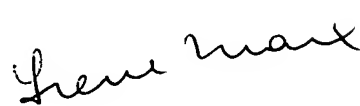
NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Satyendra K. Singh
Patent Examiner
Art Unit 1657


IRENE MARX
PRIMARY EXAMINER